UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MICHAEL J. WARING, and ELIZABETH JACQUES

Appeal No. 2006-2797
Application No. 09/341,821

ON BRIEF

Before ADAMS, MILLS, and LEBOVITZ, Administrative Patent Judges.

LEBOVITZ, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to an aerosol barrier vessel comprising a wound gel. The examiner has rejected the claims as obvious over prior art. We have jurisdiction under 35 U.S.C. § 134. We affirm-in-part.

Background

The application relates to multi-dose wound gels. Specification, page 1, lines 7-10. "The gels are usually packaged in a tube and applied to the wound from the tube." Id., page 1, lines 28-29. "If packaged in a multi-dose tube there is a risk with some gels that once the tube is opened, bacteria will enter the tube and proliferate in

the gel." Id., page 1, lines 30-33. This has caused manufacturers to add preservatives to gels. Id., page 1, lines 33-35. "Some health care professionals are reluctant to introduce preservatives to a wound and so use single dose tubes containing sterile gel." Id., page 1, lines 35-37. The application describes a solution to this problem by packaging wound gels in barrier aerosol vessels which minimize contamination once opened, and thus do not require the addition of preservatives. Specification, page 2, lines 9-14.

Claim construction

Claims 1-6, 8-10, 13-15, and 17-20, which are all the pending claims in this application, are on appeal. There are three prior art rejections, each involving a different set of claims (1-4, 13, and 17; 5, 6, 10, 14, 15, and 18; and 8, 9, 19, 20). Brief, page 2. The claims stand or fall together in each of the three sets because Appellants have grouped the claims together under a single heading without providing separate reasons for patentability for any individual claims. 37 CFR ¶ 41.37(c)(vii). We select a single claim from each set to decide the appeal as to the ground of rejection.

Claims 1-4, 13, and 17

1. A self-sealing barrier aerosol vessel containing multiple doses of a wound gel for the treatment of wounds.

Claims 5, 6, 10, 14, 15, and 18

5. A vessel as claimed in claim 1 wherein the gel comprises:
(a) from about 0.05% to 10% by weight of a natural gelling agent;
(b) from about 1.0% to 10% by weight of a hydrocolloid;
(c) from about 5.0% to 30.0% by weight of an alkylene glycol; and
(d) at least 50% by weight of water.

Claims 8, 9, 19, 20

For reasons discussed below, although claims 8 and 9 were not separately argued, we have addressed them separately.

8. A method of making a self-sealing barrier aerosol vessel comprising multiple doses of a wound gel, the method comprising the steps of:
(i) filling an inner container with gel, said inner container being contained within an outer casing container;
(ii) sealing the inner container with an opening valve; and
(iii) introducing a pressure medium between the inner container and the outer casing container.

9. A method of making a self-sealing barrier aerosol vessel comprising multiple doses of a wound gel, the method comprising the steps of:
(i) filling an inner container with non-sterile gel, said inner container being contained within an outer casing container;
(ii) sealing the inner container with an opening valve;
(iii) sterilizing the vessel and gel contained within it; and
(iv) introducing a pressure medium between the inner container and the outer casing container.

Claim 1 is drawn to a self-sealing barrier aerosol vessel. The specification explains that a barrier aerosol vessel is "of the type where the product to be dispensed and the pressure generating media, ie [sic] the propellant, are maintained in isolation through separation on opposite sides of a barrier." Specification, Page 2, lines 14-17. The specification describes "[t]hree main variants of barrier vessels" which are known in the prior art. Id., page 2, line 33-page 3, line 33. Each contains two separate compartments, one holding the product, and the other, the gas propellant which is used

to expel the product from the vessel. The gas-filled compartment is separated by a "barrier" from the product-filled compartment. When the vessel is opened, the pressure in the product-filled compartment is reduced, causing the gas-filled compartment to push against the product-filled compartment and expel the product from it. Id., page 3.

The barrier aerosol is "self-sealing." This phrase was added by an amendment filed September 3, 2003. The specification does not provide a definition of what it means to be "self-sealing" nor a description of the structure necessary to meet this limitation. However, claims "'must be read in view of the specification, of which they are a part.' .... [T]he specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" Phillips v. AWH Corp., 415 F.3d 1303, 1315, 75 USPQ2d 1321, 1327 (Fed. Cir. 2005) (internal citations omitted).

According to the specification, "because there is positive pressure in the container, the vessel can be made to be self-sealing." Specification, page 2, lines 18-20. "This aids maintenance of product [wound gel] sterility." Id., page 2, lines 20-21. It is also stated that, when the product container is sealed with the "opening valve" after filling and steam sterilization, "pressure medium can then be introduced [into the second compartment] without compromising the sterility of the product." Id., page 4, lines 6-11; page 4, line 34-page 5, line 5. Experiments that mimicked clinical use (i.e., discharge of gel from the opening valve) were performed to show that that "micro-organisms do not proliferate in the gel contained in the barrier vessel." Id., page 8, line 28-page 9, line 17. In view of the specification's reference to the opening valve with respect to maintaining wound gel sterility, we interpret the claimed requirement that the vessel is "self-sealing"

to be a property of the opening valve. We further construe "self-sealing" to have its "ordinary and customary meaning" (Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582, 39 USPQ2d 1573, 1576 (Fed. Cir. 1996)), i.e., to seal by itself ("self") without assistance.

Making the vessel "self-sealing" protects the product contained in the aerosol vessel from contamination by sealing it up after the product has been discharged. This is consistent with the vessel's purpose "to package a [wound] gel in multi-dose packaging which minimises contamination once opened." Id., page 2, lines 9-11. Neither the claims nor the specification require the self-sealing opening valve to have a particular structure.

In sum, we construe "self-sealing barrier aerosol vessel" to be a vessel having a first compartment for containing the wound gel and second compartment, which is isolated from it, that contains pressurized gas to facilitate discharge of the wound gel from the vessel. The first compartment comprises a valve or port, through which gel can be introduced into the vessel or discharged from it, and which seals up by itself after a single dosage of gel is expelled from the vessel.

Anticipation

Claims 1-4, 13 and 17 stand rejected under 35 U.S.C. § 102(b) as anticipated by Jass.[1]

[1] Jass et al. (Jass), U.S. Pat. No. 3,976,223, issued Aug. 24, 1976

Jass discloses a "valve-actuated aerosol for separately storing and simultaneously dispensing" flowable material. Jass, Abstract. As shown in Fig. 1, the package comprises two separate chambers (inner container [4] and outer container [2]) which are filled with "flowable" materials. The materials are dispensed through a "dispensing valve" [14] using a "valve actuator" [16]. The package also contains a pressure sealed lower chamber [B]. When the dispensing valve [14] is opened ..., the pressurized gas is the lower pressure sealed chamber [B] causes the piston to move away from the container bottom and toward the dispensing valve end of the container." Id., column 2, lines 57-62. The piston movement pushes the materials in the inner and outer containers through the dispensing valve. Jass descries the use of the aerosol package to dispense a "strippable gel bandage" for burn treatment. Id., column 9, line 16-column 10, line 29.

The Examiner takes the position that Jass describes an aerosol package that meets all the limitations of claim 1. For the claimed requirement that the vessel contain "multiple doses of a wound gel," the Examiner relies on Jass's disclosure (column 4, lines 52-56) that the metered amounts of material are dispensed from the package, implying that it contained multiple doses. Answer, page 5, lines 16-18. The Examiner states that "[t]he cut off of the flow as well as the self-sealing properties of the aerosol inherently prevent contamination of the content of the aerosol." Id., page 5, lines 18-20.

Appellants argue that "the container in Jass et al. is not self-sealing as required in the rejected claims." Brief, page 3. They contend that the "self-sealing plug in the container bottom" described by Jass is used to keep the lower chamber of pressured with gas, not to self-seal the container to avoid contamination. Id.

To anticipate, every element and limitation of the claimed invention must be found in a single prior art reference, arranged as in the claim. Karsten Mfg. Corp. v. Cleveland Golf Co., 242 F.3d 1376, 1383, 58 USPQ2d 1286, 1291 (Fed. Cir. 2001). We concur with the Examiner that Jass's "valve-actuated aerosol package" contains all the elements of the claimed "self-sealing barrier aerosol vessel," anticipating claim 1.

Jass's dispensing valve is kept shut with a compression spring [30] that prevents the flowable materials present in the containers from entering into the exit passageway. Jass, column 3, lines 28-47. The exit ports are opened by depressing the compression spring to actuate the dispensing valve. Id., column 4, lines 35-40. Once actuated, the "the gas under pressure in pressure tight chamber B" forces the piston upward, pushing the flowable materials through the exit passageway and out through the dispensing valve. Id., column 4, lines 38-45. As a result, "a uniform, metered amount of the flowable material" is discharged from the package. Id., column 4, lines 46-58. Jass indicates that "dispensing valve assembly" forms "a pressure tight closure when the valve is closed. Id., column 3, lines 20-24. This structure described by Jass can be characterized as "self-sealing" since the compression spring [30] in combination with the lower pressurized container keep the valve shut. Jass states that the "relative metering" of the flowable material from the container "is constant throughout the life of the dispenser," indicating that it contains "multiple doses," as required by claim 1. Id., column 4, line 66-column 5, line 2.

Appellants state that the "self-sealing plug" at column 2, lines 53-57 of Jass, relates to the "pressure sealed chamber," and is not "self-sealing" as required by the claims. Brief, page 3. We agree that the self-sealing plug described by Jass is for the

purpose of sealing the lower chamber. However, this disclosure is different from the description of the dispensing valve (as discussed above) which we have concluded satisfies the claimed requirement that the vessel is "self-sealing."

Appellants contend that the Jass's package does not "address the avoidance of contamination during its use," the advantage they describe in the specification for the claimed subject matter. Brief, page 3. As pointed out by the Examiner, this limitation is not recited in the claims. Answer, page 5, ¶ 2. More to the point is whether Jass describes an aerosol package that meets all the expressly recited limitations of claim 1. For the reasons discussed above, we find that it does. Accordingly, we conclude that there is adequate evidence to establish a case of prima facie anticipation of claim 1. Appellants have not provided convincing arguments to rebut it. Claims 2-4, 13, and 17 fall together with claim 1.

Obviousness

Jass in view of Court

Claims 5, 6, 10, 14, 15, and 18 stand rejected under 35 U.S.C. § 103(a) as obvious over Jass in view of Court.[2]

Claim 5 requires that the gel comprises four components (a)-(d). The Examiner cites Court for teaching a wound dressing that contains these four components, arguing that it would have been obvious to have replaced the wound dressing in Jass with the gel disclosed in Court for the reason that Jass teaches its package as useful for

[2] Court et al. (Court), EP 0 666 081 A1, published Aug. 9, 1995

delivering "flowable materials," including wound gels that have the characteristics of the composition described by Court. Answer, page 7.

The examiner bears the initial burden of showing unpatentability. See e.g., In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A prima facie case of obviousness requires evidence that the prior art suggested to those of ordinary skill in the art that they should make the claimed subject matter, and that those skilled in the art would have been motivated to do so with a reasonable expectation of success. See In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970); In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

Jass teaches its package for "separately storing and simultaneously dispensing ... a plurality of flowable materials." Jass, Abstract. Jass describes his aerosol container as a solution to prior art attempts to package materials in a multi-compartment aerosol container which must be kept separate from each other until used. Id., column 1, lines 13-65. "The typical examples of materials which react when mixed and, because of such reaction, must be kept separated from each other until used are ... dyes and developers for hair colorings, epoxy resin based paints and cements which harden upon mixing." Id., column 1, lines 30-36. Jass's strippable gel bandage is comprised of two phases that are separately stored in the two-compartment aerosol package. When expelled on to the skin, they gel "at the site of use." Id., column 9, lines 42-43.

Court teaches a composition in which all the ingredients are present together, and does not disclose or suggest that they require separate compartmentalization. We see no reason which would have motivated the skilled artisan to have used Jass's two-

compartment container for storing Court's single composition. This rejection is reversed.

Sperry in view of Jass

Claims 8, 9, 19, and 20 stand rejected under 35 U.S.C. § 103(a) over Sperry[3] in view of Jass.

Although Appellants did not separately argue any of the claims in this group, because we found claim 8 to be anticipated, rather than obvious over the prior art, we decided to separately address claims 9, 19, and 20.

Claim 8

Claim 8 has three steps: 1) filing the inner container of the aerosol vessel with gel; 2) sealing it with an opening valve; and 3) introducing pressure into the vessel "between the inner container and the outer casing container." The Examiner states that these three steps are taught by Sperry. Answer, page 9. She concludes that it would have been obvious to have used Sperry's container for a wound treating composition as described in Jass, but does not clearly articulate the motivation for making this combination. Id.

Appellants argue that Sperry does not "teach or suggest a dispensing vehicle that contains multiple doses of wound-treating material." Brief, page 4. They also argue that Sperry teaches dispensing a liquid, and not a wound gel. Id., page 5.

We do not find Appellants arguments persuasive. Sperry teaches that an aerosol container for dispensing wound cleaning compositions can be sterilized after filling, either by irradiation or autoclaving. Sperry, column 2, lines 64-68; column 6, lines 20-

[3] Sperry et al. (Sperry), U.S. Pat. No. 5,059,187, issued Oct. 22, 1991

23. When autoclaving is used to sterilize the container, the container is filled with wound cleansing solution, sealed, autoclaved, and then filled with a gas propellant. Id., column 5, lines 8-21. In our view, these steps are the logical and necessary steps that would be required to prepare Jass's aerosol container for use. Jass's container holds gel in an inner container and therefore must be filled with it, meeting step (i) of claim 8; it also has an "opening valve" that seals the inner container (column 3, lines 20-28, stating that the "dispensing valve assembly" forms "a pressure tight closure when the valve is closed") as required in step (ii); a pressure medium is introduced "between the inner container and the outer casing container," meeting step (iii) (Fig. 2, compare [B] and [54]; the gas is introduced into B as described on column 4, lines 24-28).

We recognize that Jass does not expressly state that the three steps required by claim 8 are carried out, but such steps would be necessary to prepare his disclosed aerosol package filled with the components of the gel bandage. To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." Atlas Powder Co. v. Ireco, Inc., 190 F.3d 1342, 1346, 51 USPQ2d 1943, 1945 (Fed. Cir. 1999). "Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates." Id., 190 F.3d at 1347; 51 USPQ2d at 1946. For the foregoing reason, we conclude that these conditions are met here.

We designate this as a new grounds of rejection because we are not relying on the combination of references upon which the Examiner based the § 103 rejection. Rather, we are setting forth a new ground of rejection of claim 8 as anticipated under § 102(b) by Jass.

Claims 9, 19, and 20

For claims 9, 19, and 20, which require a sterilizing step, we concur with the Examiner that such claims are obvious over Jass and Sperry, but for different reasons than stated by the Examiner.

In making an obviousness determination, it is necessary to consider the differences between the claimed invention and the prior art in the context of the level of the person of ordinary skill in the art. Graham v. John Deere Co., 383 U.S. 1, 13-14, 148 USPQ 459, 465 (1966). In this case, the difference between the claimed subject matter and Jass is that the Jass does not teach or expressly suggest a step in which the vessel and gel are sterilized as required by the claims.

As observed by the Examiner, this deficiency is met by Sperry. Sperry teaches that wounds are normally cleaned and irrigated with sterile solutions. Sperry, column 1, lines 10-25 and 60-63. The compositions can be sterilized prior to introduction into the container, or when already loaded into the container as described by Sperry (column 2, lines 60-68; column 5, lines 7-21).

In order to combine references, there must be some teaching, suggestion, or motivation found in the prior art or from the general knowledge available to the skilled worker. "[T]he teaching, motivation, or suggestion may be implicit from the prior art as a whole, rather than expressly stated in the references. The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." In re Kahn, 441 F.3d 977, 987-88, 78 USPQ2d 1329, 1336

(Fed. Cir. 2006). Here, we find that the nature of the problem – to treat a burn wound – would have suggested to the skilled worker (e.g., a healthcare provider) that Jass's wound gel bandage requires sterilization, and would have been motivated to accomplish it according to Sperry, as a choice of a conventional technology for accomplishing sterilization. Accordingly, it is our conclusion that claims 9, 19, and 20 are obvious over the combination of Sperry and Jass. Because our reasoning in affirming this rejection differs from the Examiner, we designate it as a new ground of rejection to provide Appellants with a fair opportunity to respond to it.

In response to arguments made by Appellants distinguishing Sperry on the basis that it does not teach "dispensing multiple doses," we concur with the Examiner that Sperry is "relied upon for the solely teaching of the method of making the aerosol." Answer, Page 10.

Other issues

Appellants have admitted in their application that barrier aerosol vessels were known in the prior art. Specification, pages 2-4. Upon return of this application to the technology center, we suggest that the Examiner reconsider the prior art as it pertains to claims 5, 6, 10, 14, 15, and 18 and make specific findings on whether any of the prior art barrier aerosol vessels are "self-sealing" and for use with a single composition in contrast to Jass's teaching. Among the prior art, we call the Examiner's attention to pages 1680-81 of Remington,[4] particularly Fig. 7 which shows a barrier aerosol vessel with a metering valve.

[4] Remington: The Science and Practice of Pharmacy, Vol. II, pp. 1680-81 (1995)

Summary

We affirm the rejection of claims 1-4, 13, and 17 as anticipated by prior art and the rejection of claim 9, 19, and 20 as obvious over prior art. We set forth a new grounds of rejection for claim 8 as anticipated by prior art. The rejection of claims 5, 6, 10, 14, 15, and 18 is reversed.

Time Period for Response

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 C.F.R. § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .

(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

AFFIRMED-IN-PART/37 C.F.R. § 41.50(b)

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